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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,413	04/21/2008	Mark G Palermo	33727-US-PCT	1934

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NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.  
220 MASSACHUSETTS AVENUE  
CAMBRIDGE, MA 02139

EXAMINER
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NIEBAUER, RONALD T

ART UNIT	PAPER NUMBER
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1654

NOTIFICATION DATE	DELIVERY MODE
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10/04/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/594,413	<b>Applicant(s)</b> PALERMO ET AL.	
	<b>Examiner</b> RONALD T. NIEBAUER	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

Claims 1-26 are under consideration.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 24 in part, drawn to the first compound recited in claim 24 (i.e. N-[1 - Cyclohexyl-2-oxo-2-(6-phenethyl-octahydro-pyrrolo[2,3-c]pyridin-1-yl)-ethyl]-2- methylamino-acetamide).

Group 2, claim(s) 24 in part, drawn to the 2nd compound recited in claim 24.

Group 3, claim(s) 24 in part, drawn to the 3rd compound recited in claim 24.

Group 4, claim(s) 24 in part, drawn to the 4th compound recited in claim 24.

Group 5, claim(s) 24 in part, drawn to the 5th compound recited in claim 24.

Group 6, claim(s) 24 in part, drawn to the 6th compound recited in claim 24.

Group 7, claim(s) 24 in part, drawn to the 7th compound recited in claim 24.

Group 8, claim(s) 24 in part, drawn to the 8th compound recited in claim 24.

Group 9, claim(s) 24 in part, drawn to the 9th compound recited in claim 24.

Group 10, claim(s) 24 in part, drawn to the 10th compound recited in claim 24.

Group 11, claim(s) 24 in part, drawn to the 11th compound recited in claim 24.

Group 12, claim(s) 24 in part, drawn to the 12th compound recited in claim 24.

Group 13, claim(s) 24 in part, drawn to the 13th compound recited in claim 24.

Group 14, claim(s) 24 in part, drawn to the 14th compound recited in claim 24.

Group 15, claim(s) 24 in part, drawn to the 15th compound recited in claim 24.

Group 16, claim(s) 24 in part, drawn to the 16th compound recited in claim 24.

Group 17, claim(s) 24 in part, drawn to the 17th compound recited in claim 24.

Group 18, claim(s) 24 in part, drawn to the 18th compound recited in claim 24.

Group 19, claim(s) 24 in part, drawn to the 19th compound recited in claim 24.

Group 20, claim(s) 24 in part, drawn to the 20th compound recited in claim 24.

Group 21, claim(s) 24 in part, drawn to the 21st compound recited in claim 24.

Group 22, claim(s) 24 in part, drawn to the 22nd compound recited in claim 24.

Group 23, claim(s) 24 in part, drawn to the 23rd compound recited in claim 24.

Group 24, claim(s) 24 in part, drawn to the 24th compound recited in claim 24.

Group 25, claim(s) 24 in part, drawn to the 25th compound recited in claim 24.

Group 26, claim(s) 24 in part, drawn to the 26th compound recited in claim 24.

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Group 27, claim(s) 24 in part, drawn to the 27th compound recited in claim 24.  
Group 28, claim(s) 24 in part, drawn to the 28th compound recited in claim 24.  
Group 29, claim(s) 24 in part, drawn to the 29th compound recited in claim 24.  
Group 30, claim(s) 24 in part, drawn to the 30th compound recited in claim 24.  
Group 31, claim(s) 24 in part, drawn to the 31st compound recited in claim 24.  
Group 32, claim(s) 24 in part, drawn to the 32nd compound recited in claim 24.  
Group 33, claim(s) 24 in part, drawn to the 33rd compound recited in claim 24.  
Group 34, claim(s) 24 in part, drawn to the 34th compound recited in claim 24.  
Group 35, claim(s) 24 in part, drawn to the 35th compound recited in claim 24.  
Group 36, claim(s) 24 in part, drawn to the 36th compound recited in claim 24.  
Group 37, claim(s) 24 in part, drawn to the 37th compound recited in claim 24.  
Group 38, claim(s) 24 in part, drawn to the 38th compound recited in claim 24.  
Group 39, claim(s) 24 in part, drawn to the 39th compound recited in claim 24.  
Group 40, claim(s) 24 in part, drawn to the 40th compound recited in claim 24.  
Group 41, claim(s) 24 in part, drawn to the 41st compound recited in claim 24.  
Group 42, claim(s) 24 in part, drawn to the 42nd compound recited in claim 24.  
Group 43, claim(s) 24 in part, drawn to the 43rd compound recited in claim 24.  
Group 44, claim(s) 24 in part, drawn to the 44th compound recited in claim 24.  
Group 45, claim(s) 24 in part, drawn to the 45th compound recited in claim 24.  
Group 46, claim(s) 24 in part, drawn to the 46th compound recited in claim 24.  
Group 47, claim(s) 24 in part, drawn to the 47th compound recited in claim 24.  
Group 48, claim(s) 24 in part, drawn to the 48th compound recited in claim 24.  
Group 49, claim(s) 24 in part, drawn to the 49th compound recited in claim 24.  
Group 50, claim(s) 24 in part, drawn to the 50th compound recited in claim 24.  
Group 51, claim(s) 24 in part, drawn to the 51st compound recited in claim 24.  
Group 52, claim(s) 24 in part, drawn to the 52nd compound recited in claim 24.  
Group 53, claim(s) 24 in part, drawn to the 53rd compound recited in claim 24.  
Group 54, claim(s) 24 in part, drawn to the 54th compound recited in claim 24.  
Group 55, claim(s) 24 in part, drawn to the 55th compound recited in claim 24.  
Group 56, claim(s) 24 in part, drawn to the 56th compound recited in claim 24.  
Group 57, claim(s) 24 in part, drawn to the 57th compound recited in claim 24.  
Group 58, claim(s) 25 in part, drawn to the 1st compound recited in claim 25 (i.e. N-[1-cyclohexyl-2-oxo-2-(6-phenethyl-octahydro-pyrrolo[2,3-c]pyridin-1-yl)-ethyl]-2- methylamino-propionamide).  
Group 59, claim(s) 25 in part, drawn to the 2nd compound recited in claim 25.  
Group 60, claim(s) 25 in part, drawn to the 3rd compound recited in claim 25.  
Group 61, claim(s) 25 in part, drawn to the 4th compound recited in claim 25.  
Group 62, claim(s) 25 in part, drawn to the 5th compound recited in claim 25.  
Group 63, claim(s) 25 in part, drawn to the 6th compound recited in claim 25.  
Group 64, claim(s) 26 in part, drawn to the 1st compound recited in claim 26 (i.e. (S)-N-{(S)-1-Cyclohexyl-2-oxo-2-[(S)-2-(3-phenoxy-phenyl)-pyrrolidin-1-yl]-ethyl}-2- methylamino-propionamide).  
Group 65, claim(s) 26 in part, drawn to the 2nd compound recited in claim 26.  
Group 66, claim(s) 26 in part, drawn to the 3rd compound recited in claim 26.

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Group 67, claim(s) 26 in part, drawn to the 4th compound recited in claim 26.

Group 68, claim(s) 26 in part, drawn to the 5th compound recited in claim 26.

Group 69, claim(s) 26 in part, drawn to the 6th compound recited in claim 26.

Group 70, claim(s) 22-23, drawn to a methods of treating diseases.

Claims 1-21 link(s) inventions of groups 1 to 69. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 1-21. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

**It is noted that this is a group restriction, not an election of species.** The election of species requirement is listed below.

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It is noted that for whichever group is elected applicant it is suggested that applicant provide a structural representation of the particular compound. Furthermore, if Applicant feels that certain Groups (compounds recited within the Group) belong in the same Group, then Applicants should present arguments as to which Groups belong with one another and why these Groups belong together, i.e. they share a **significant** common core.

The inventions listed as Groups 1-70 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: PCT Rule 13.2 defines “special technical features” as “those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.” According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. In the instant case, the compounds of claims 1-69 are structurally distinct. Further, the claims are drawn to compounds or methods of administering compounds which are described as inhibitors of IAP. Sharma et al (WO 2004/005248) also teach compounds that are inhibitors of IAP (abstract, examples 1-29) and methods of administering such compounds (claims 10-11) where the compounds have the core recited in formula I of the instant claims. Thus any technical features are not a contribution over the prior art and the claims lack unity.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

### *Election of Species*

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If group 70 is elected, species election is necessary for:

1. **Compound** – a specific species of compound should be identified. Applicant should uniquely identify the compound such that structure is clear and such that all variable groups are uniquely defined.
2. **Patient population** – a specific disease should be identified.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

The following claim(s) are generic: claims 1-26.

There is an examination and search burden for the species due to their mutually exclusive characteristics. Each of the species are structurally distinct and one of skill in the art would not recognize that every alternative would behave in the same way. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the



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examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim

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will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/  
Primary Examiner, Art Unit 1654

/Ronald T Niebauer/  
Examiner, Art Unit 1654